

Office Action Summary

Application No.

08/896,406

Applicant(s)

Wolfgang Barnikol

Examiner

ANISH GUPTA

Group Art Unit

1653



☒ Responsive to communication(s) filed on Sep 29, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 6-9 and 11-15 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 6-9 and 11-15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The amendment filed 9-29-00 is acknowledged. The amendment canceled claims 10 and 16 and amended claims 6, 9, and 11. Claims 6-9 and 11-15 are pending in this application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 9, 10 and 15, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 6-9, and 11-13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Potzschke et al. (U) for the reasons set forth in the previous office actions and the reasons set forth below.

3. Claims 11 and 15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Potzschke et al. for the reasons set forth in the previous office actions and the reasons set forth below.

For both rejections, Applicants argue similar points, which have been addressed below.

Applicants argue that the claims have now been limited to a preparative method and exclude an analytical method. The Poetzschke does not anticipated the claimed preparative method. "In an analytical method, the test sample is small and is lost by the method of detection. In a preparative method, the sample must survive the detection process (preferably with high yield). Thus, that one is able to detect the separation of cross-linked hyper polymeric hemoglobin by its molecular weight, is no guarantee that one can preserve such fractions separated by molecular weight."

Applicant's arguments filed 9-29-00 have been fully considered but they are not persuasive.

Applicants do not explain how the amended claims are now distinguished over an analytical method. It seems since the claims have been amended to recite "[s]eparating the hyper polymeric hemoglobin into different fractions based its molecular weight," the claims are now distinct over an analytical method. However, Applicants arguments do establish how such a limitation excludes analytical methods. Moreover, the applicants have not provided support within the specification that such a limitation distinguishes the claimed method from an analytical method.

Assuming, arguendo, such a limitation does exclude analytical methods, the reference still anticipates the claimed invention. The reference teaches that the hyper polymeric hemoglobin can be purified using Sepharcryl S-400 high resolution gel. Thus, the purification procedure would necessarily result in separating the hyper polymeric hemoglobin into different fractions based its molecular weight. Furthermore, the reference teaches that hyper polymers were well fractionable in ultrafiltration (see page 290). Thus, the reference still anticipates the claimed invention.

Applicants argue the following points:

4. Claims 6-9, 11-15 remain under 35 U.S.C. 103(a) as being unpatentable over Potzschke et al.(U) in view of Bonhard et al. for the reasons set forth in the previous office actions and the reasons set forth below.

Applicants argue that the use of ammonium sulfate in the claimed method is used for the separation of cross linked hemoglobin from cross linked hemoglobin based on molecular weight.

Applicant's arguments filed 9-29-00 have been fully considered but they are not persuasive.

The claims do not state that the use of ammonium sulfate results in the purification of cross linked hemoglobin from cross linked based on molecular weight. Assuming, arguendo, the claims did state this, the use of ammonium sulfate would necessarily result in such a separation. This is because the ammonium sulfate would be applied to a similar reaction mixture as claimed. The reference of Bonhard et al. provides motivation for the use of ammonium sulfate. The motivation being the separation of uncross-linked hemoglobin from cross-linked hemoglobin. The motivation need not be the same as Applicants to establish a prima facie obviousness rejection (MPEP 2143.01). All is required is a motivation to modify the primary reference with a reasonable expectation of success. Here, of Bonhard et al. teach that ammonium sulfate can separate the uncross-linked hemoglobin from cross-linked hemoglobin. Thus, one would be motivated to use ammonium sulfate to separate the cross linked hyperpolymeric hemoglobin from uncross-linked hemoglobin. Thus, the references combined establish a prima facie obviousness.

Rejection is maintained.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. ~~Any inquiry concerning this communication or earlier communications from the examiner should be directed to~~
Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are

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unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Anish Gupta

Christopher S. F. Low

CHRISTOPHER S. F. LOW
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